UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

UNITED STATES OF AMERICA, *ex rel.* [UNDER SEAL],

Plaintiff and Relator,

v.

[UNDER SEAL],

Defendants.

FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

2:19CV2618 TLN KJN

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

DO NOT ENTER ON PACER

DO NOT PUT IN PRESS BOX

[FILED IN CAMERA AND UNDER SEAL]

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA, SACRAMENTO DIVISION

UNITED STATES *ex rel.* Thomas Aland;

STATE OF ARKANSAS *ex rel.* Thomas Aland;

STATE OF CALIFORNIA *ex rel.* Thomas Aland;

STATE OF COLORADO *ex rel.* Thomas Aland;

STATE OF CONNECTICUT *ex rel.* Thomas Aland;

STATE OF DELAWARE *ex rel.* Thomas Aland;

DISTRICT OF COLUMBIA *ex rel.* Thomas Aland;

STATE OF FLORIDA *ex rel.* Thomas Aland;

STATE OF GEORGIA *ex rel.* Thomas Aland;

Case No. _____

FILED UINDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

DO NOT PLACE IN PRESS BOX
DO NOT ENTER ON PACER

STATE OF HAWAII *ex rel.* Thomas Aland;

STATE OF ILLINOIS *ex rel.* Thomas Aland;

STATE OF INDIANA *ex rel.* Thomas Aland;

STATE OF IOWA *ex rel.* Thomas Aland

STATE OF LOUISIANA *ex rel.* Thomas Aland;

STATE OF MARYLAND *ex rel.* Thomas Aland;

COMMONWEALTH OF MASSACHUSETTS *ex rel.* Thomas Aland;

STATE OF MICHIGAN *ex rel.* Thomas Aland;

STATE OF MINNESOTA *ex rel.* Thomas Aland;

STATE OF MONTANA *ex rel.* Thomas Aland;

STATE OF NEVADA *ex rel.* Thomas Aland;

STATE OF NEW HAMPSHIRE *ex rel.* Thomas Aland;

STATE OF NEW JERSEY *ex rel.* Thomas Aland;

STATE OF NEW MEXICO *ex rel.* Thomas Aland;

STATE OF NEW YORK *ex rel.* Thomas Aland;

STATE OF NORTH CAROLINA *ex rel.* Thomas Aland;

STATE OF OKLAHOMA *ex rel.* Thomas Aland;

STATE OF RHODE ISLAND *ex rel.* Thomas Aland;

STATE OF TENNESSEE, *ex rel.* Thomas Aland;

STATE OF TEXAS *ex rel.* Thomas Aland;

STATE OF VERMONT *ex rel.* Thomas Aland;

COMMONWEALTH OF VIRGINIA *ex rel.* Thomas Aland; and

STATE OF WASHINGTON *ex rel.* Thomas Aland,

Plaintiffs,

vs.

US WORLDMEDS LLC,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Plaintiff/Relator Thomas Aland brings this action on behalf of Plaintiff United States and the Plaintiff States (the United States and Plaintiff States are collectively referred to herein as the "Government") under the Federal False Claims Act, 31 U.S.C. § 3729 – 3733 (the "False Claims Act" or "FCA"), and the false claims acts of the respective Plaintiff States against Defendant US WorldMeds LLC ("USWM") to recover, among other things, damages and penalties owed as a result of a systemic fraud that USWM has perpetrated against the

Government.

2. Specifically, USWM has engaged in a series of deceptive and fraudulent practices to induce prescriptions of its drug, Lucemyra, to be charged against Government healthcare programs, including Medicare and Medicaid. The illicit practices include promoting the drug for off-label and medically unnecessary indications that pose substantial health and safety risk to patients. To induce these off-label and medically unnecessary prescriptions, USWM employees have paid kickbacks to doctors, pharmacists, and others to not only prescribe Lucemyra, but to fabricate information about the use of the drug and the patients' medical history necessary to get the prescriptions authorized and reimbursed by Government healthcare programs. The bribes have come in the form of lucrative payments to doctors to engage in bogus "speaker programs," and, in some cases, direct cash payments from USWM sales representatives to pharmacy employees and others.

3. These illicit practices stem in large part from quarterly sales quotas imposed upon USWM salespeople that are based not on the number of prescriptions written, but on the volume of pills that a doctor prescribes. To incentivize the sales representatives to meet the quotas, the company gives the salespeople double credit for those prescriptions where doctors prescribe two bottles (192 pills) of the drug for a patient, when the typical on-label and medically necessary use of the drug calls for only one bottle (96 pills). As a result, USWM representatives have resorted to illegal practices, including paying bribes to doctors, pharmacists and others to cause Lucemyra scripts to be written and dispensed, making false statements to Government healthcare providers in the process. Many of these practices are known and encouraged by USWM management.

4. This is not USWM's first offense. USWM recently paid the U.S. Department of Justice $17.5 million to resolve alleged False Claims Act violations for paying kickbacks to patients and physicians to improperly induce prescriptions of two other USWM drugs. As part of that resolution, USWM entered into a five-year "Corporate Integrity Agreement" ("CIA") with the US Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") designed to ensure that USWM's marketing and sales practices comply with the law.

Despite the resolution and the CIA, USWM continues to engage in illicit sales practices to maximize its revenue at the expense of patient safety and taxpayer dollars.

5. Plaintiff Aland is a USWM sales representative who has witnessed and gathered evidence of these illegal practices. He now seeks recovery on behalf of the Government for USWM's illicit scheme.

II. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the federal FCA claims under 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1331 and 1345. The Court has subject matter jurisdiction over the Plaintiff State claims under 31 U.S.C. § 3732(b), because the claims seek recovery under state law for funds paid by the Plaintiff States and the action arises from the same transactions and occurrences as the federal FCA claim.

7. This Court has personal jurisdiction over USWM because section 3732(a) of the FCA permits worldwide service of process, and USWM is a United States domiciled company doing business throughout the United States. Venue is appropriate in this District under section 3732(a) of the FCA because USWM transacts business in this District, including Sacramento, can be found in this District, and because several of the illegal acts proscribed by the FCA occurred in this District.

III. PARTIES

8. Plaintiff Aland is an individual domiciled in Pittsburgh, Pennsylvania. He is a sales representative for USWM.

9. USWM is a drug manufacturer headquartered in Louisville, Kentucky. It sells its drug Lucemyra throughout the United States, including California.

IV. GENERAL ALLEGATIONS

A. Lucemyra and Its Limited Indication and Coverage.

10. Lucemyra (generic name lofexidine) is a prescription drug manufactured by USWM. It is a non-opioid compound, known as a central alpha-2 adrenergic agonist, indicated for mitigation of opioid withdrawal symptoms to facilitate *abrupt* opioid discontinuation in adults. It was approved for sale in the United States by the U.S. Food and Drug Administration

("FDA") on May 16, 2018.

11. Lucemyra's indication is limited to patients who are discontinuing opioids abruptly, that is patients who are suddenly and completely stopping opioid use. In approving the drug, the FDA specifically declined to approve Lucemyra for use with patients who are tapering off of opioids or who are using long-acting opioids such as buprenorphine. According to the FDA's Multi-Discipline Review for Lucemyra, the drug's "indication should be restricted to abrupt or acute withdrawal of short-acting opioids because long-acting opioids and opioid taper were not studied and the benefit of the studied clinical situations cannot be extrapolated to these situations."

12. In addition to having no proven benefit in treating withdrawal symptoms associated with tapering, there are several serious side effects associated with Lucemyra. First, Lucemyra can cause hypotension (decrease in blood pressure), bradycardia (decrease in pulse), and syncope (loss of consciousness). Second, Lucemyra prolongs the QT interval—a measure of delay in ventricular repolarization, which means the heart muscle takes longer than normal to recharge between beats, and can result in sudden cardiac death.

13. These risks were material to the FDA's decision to limit Lucemyra's indication to withdrawal from abrupt discontinuation of short-acting opioids, such as heroin. This is because the patients in that category tend to be a younger and healthier population, whereas the patients in need of tapering typically tend to be chronic pain patients, who are typically older and have comorbidities that enhance the risks of hypotension, bradycardia, syncope, and QT prolongation associated with Lucemyra.

14. The limited indication for abrupt opioid discontinuation was a setback for USWM's commercial aspirations for Lucemyra. This setback has been exacerbated by several things. First, on October 10, 2019, HHS published a guide for clinicians on appropriate reduction and discontinuation strategies for opioid drugs, in which it recommended that clinicians generally avoid abrupt discontinuation. Specifically, the agency wrote: "Opioids should not be tapered rapidly or discontinued suddenly due to the risks of significant opioid withdrawal.... Unless there are indications of a life-threatening issue, such as warning signs of

impending overdose, HHS does not recommend abrupt opioid dose reduction or discontinuation." *See HHS Guide for Clinicians on the Appropriate Dosage Reduction of Discontinuation of Long-Term Opioid Analgesics*, at p. 1.

15. Given that Lucemyra is only indicated for abrupt opioid discontinuation, this recommendation, which is consistent with an already prevalent practice in opioid discontinuation therapy, has significantly hampered USWM's commercial prospects for Lucemyra.

16. Second, Lucemyra has cheaper and more established competition. A similar non-opioid, central alpha-2 adrenergic agonist used to treat opioid withdrawal symptoms is clonidine. Clonidine is a generic drug indicated for treatment of hypertension that has long been used off label to mitigate withdrawal symptoms associated opioid discontinuation. Clonidine is a fraction of the cost of Lucemyra. Where Lucemyra generally costs over $20 per 1.8 mg pill, a similar dosage of clonidine costs under five cents per pill.

17. For these reasons, most commercial and Government pharmacy benefit plans, including Medicare and Medicaid plans, do not include Lucemyra on their drug formularies and generally do not cover the drug. Thus, most patients prescribed Lucemyra will be responsible for the entire cost of the drug absent a special exception granted by the plan. These showings usually require a statement from the prescriber demonstrating why this Lucemyra is medically necessary and why other drugs in the class, i.e., clonidine, are not appropriate for the patient.

18. For the minority of Government and commercial plans that do contain Lucemyra on their formularies, the drug is subject to prior-authorization and/or step therapy restrictions. These restrictions generally require that the prescriber establish that the patient has a medical history of failure with clonidine or a history of intolerance to clonidine. The restrictions also generally require the prescriber to certify that the prescription is for treating withdrawal symptoms from abrupt opioid discontinuation (as opposed to tapering).

B. <u>In the Face of Commercial Challenges, USWM Has Resorted to Off-Label Marketing, Bribery, and Fraudulent Misrepresentations to Sell Lucemyra.</u>

19. The formulary exclusions and other restrictions that plans have placed on Lucemyra have dampened its outlook for commercial success. Getting the drug approved is

burdensome on providers and their staff, requiring them to fill out multiple forms, draft letters of medical necessity, and, usually, appeal the plan's initial declination of the drug. Many providers are not willing to assume this burden, particularly when there is a substantially similar and cheaper alternative—i.e., clonidine—that is covered by all plans and has no prior authorization or step therapy restrictions.

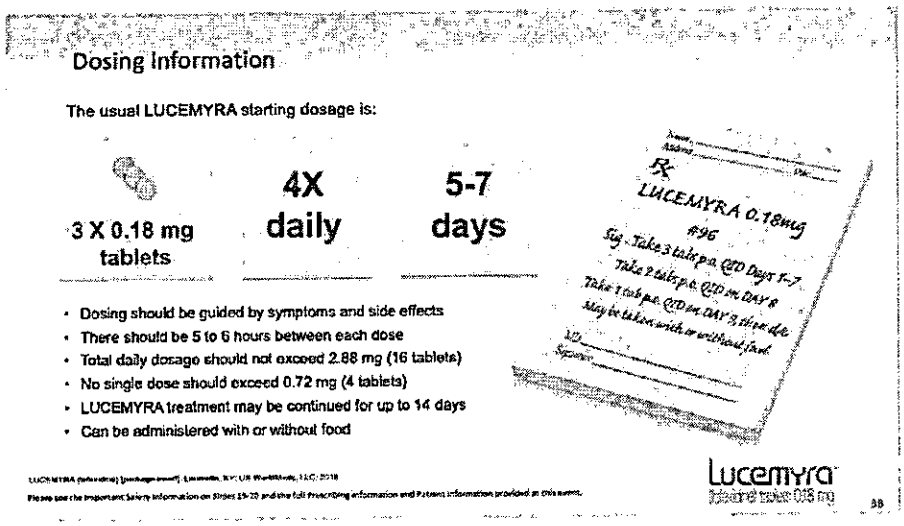
20. Faced with these challenges, USWM's management has directed and incentivized its sales employees to aggressively market Lucemyra off-label for non-indicated or medically unnecessary uses, such as to treat withdrawal symptoms of patients tapering off of opioids or to be written in excessive amounts to patients to be taken in the patients' discretion "just in case" they have withdrawal symptoms sometime in the future. These indications, when accepted by prescribers, result in far more Lucemyra pills being prescribed than if written for its indicated use to treat symptoms associated with abrupt withdrawal symptoms from opioid discontinuation.

21. To properly understand USWM's scheme to market off-label, it is important to understand the indicated dosing of Lucemyra and its standard packaging. According to Lucemyra's FDA approved label, the "*usual* LUCEMYRA starting dose is three 0.18 mg tablets taken orally 4 times daily during the period of peak withdrawal symptoms (generally the first 5 to 7 days following last use of opioid) with dosing guided by symptoms and side effect." (Emphasis added). Discontinuation should be "a gradual dose reduction over a 2- to 4- day period to mitigate Lucemyra withdrawal symptoms (e.g. reducing by 1 tablet per dose every 1 to 2 days)." The label also guides that Lucemyra "should be reduced, held, or discontinued for individuals who demonstrate greater sensitivity to Lucemyra side effects," and that "[l]ower doses may be appropriate as opioid withdrawal symptoms wane." While the maximum daily dose can be as many as 16 tablets (4 tablets 4 times a day), this is not the "usual" dose. The label further provides that Lucemyra treatment should not exceed a total of 14 days.

22. Consistent with these parameters, USWM sought and received approval for standard packaging of 36- and 96-count bottles. Importantly, the 96-count bottle perfectly aligns with the "usual" dosing described in the Lucemyra approved label. Indeed, USWM developed and received FDA approval for marketing material showing prescribers precisely how to write

prescriptions for the usual Lucemyra dose, indicating that doctors should write scripts for Lucemyra at 96 pills as follows: (1) 3 pills four 4 times daily for days 1-7; (2) 2 pills 4 times daily on day 8; and (3) 1 pill 4 times daily on day 9.

23. The following is an example of the marketing material that USWM developed to guide doctors in the appropriate dosing of Lucemyra:



24. But with the increasing obstacles with coverage and underwhelming sales, USWM management began directing sales representatives to push doctors to write scripts for two 96-pill bottles—a total of 192 pills—which is twice the "usual" dose indicated for patients. To ensure that salespeople so marketed Lucemyra, USWM took several measures, including (1) implementing aggressive sales quotas and bonus programs that incentivized sales representatives to push doctors to write for two 96-pill bottles, (2) directing salespeople to market Lucemyra for off-label tapering and medically unnecessary indications; (3) providing misleading and unapproved marketing materials to doctors instructing them to write double scripts, (4) paying doctors, pharmacists, and others bribes to induce them to write and/or obtain Government and private healthcare coverage for Lucemyra; and (5) making material misrepresentations about patients' medical history and medical necessity to obtain Government and private healthcare

coverage for Lucemyra.

USWM Has Implemented Volume-Based Sales Quotas to Improperly Incentivize Off-Label Marketing.

25. To increase sales, USWM implemented and continues to impose a nationwide sales quota program based not on the number of prescriptions written, but on the quantity of pills dispensed. Under the program, all salespeople have a goal of 110 prescriptions in their respective territories per quarter, with a minimum of 35 prescriptions. Salespeople who fall short of their quarterly quota of 35 are not eligible for any bonus. But once a sales representative meets the quota, he or she receives a retroactive per-script bonus for all 35 prescriptions plus any additional prescriptions credited to the representative that quarter. The per-script bonus is adjusted each quarter, but has ranged between $100 to $125 per script.

26. The sales quota and bonus structure by design incentivizes sales representatives to persuade doctors to write for two or more 96-pill bottles. This is because the number of prescriptions credited to each sales representative is not based on the number of individual prescriptions the doctor actually writes, but for the number of 96-pill bottles the doctor prescribes. Thus, if a doctor writes for 192 pills as opposed to 96 pills, the sales representative receives credit for *two* separate prescriptions. Likewise, if the doctor writes a single prescription for 3 bottles—288 pills—the representative gets credit for three prescriptions. Thus, sales representatives get double or triple credit when doctors prescribe two or three times the usual recommended dose of Lucemyra.

27. Importantly, prescriptions for 192 or more pills are not reasonable or necessary to treat patients undergoing abrupt opioid discontinuation. Data from the clinical studies underlying Lucemyra's FDA approval showed that the withdrawal symptoms of patients abruptly discontinuing opioids, even those who had been heavy heroin users for years, peaked on day 2, and that by day 5 through 7 were similar in severity to those of the control group receiving a placebo. Thus, it is a rare patient who would ever need anything approaching 192 pills to treat the withdrawal symptoms associated with abrupt opioid discontinuation. Indeed, for most patients, the 96-pill bottle is more than sufficient to adequately treat the withdrawal symptoms,

and many patients do not need more than the smaller dose regimen of 36 pills. USWM salespeople recognize this fact and, for this reason, many refuse to give doctors the 36-pill bottle as samples because their experience is that that quantity obviates the need for doctors to prescribe more pills.

USWM Has Directed Its Salesforce to Engage in Off-Label Marketing.

28. Because patients do not actually need 192 for Lucemyra's indicated use, USMW's management instructs its employees to market Lucemyra for off-label and medically unnecessary uses. The management that has so instructed salespeople include the USWM's national sales director, Bill Carnohan, and USWM's regional sales directors, including Chris Brown who oversees the Northeast region. These sales directors communicate these messages routinely during sales meeting and training calls, and during one-on-one ride-alongs with sales staff.

29. The specific off-label message that salespeople are directed to communicate include statements that:

- Lucemyra is safe and effective in treating patients who are tapering off of opioids over an extended period of time;
- Lucemyra is more effective and safer than clonidine in treating all withdrawal symptoms, including symptoms in those patients who are tapering off of opioids;
- That 192 pills (two bottles) is the ideal amount of pills for each patient, and that the doctors should "start low, and go slow," meaning that they should prescribe low doses over an extended period of time, and have 192 pills "just in case," the patient feels sick in the extended future; and
- In addition to writing for 192 pills, doctors should also write for at least one refill in the event the patient decides to take Lucemyra in the distant future.

30. These are not only off-label messages, they are false and misleading. *First,* Lucemyra has not been proven to be safe or effective in treating patients in the tapering context. To the contrary, the two clinical trials supporting the efficacy and safety of Lucemyra were conducted on patients physically dependent on short-acting opioids (e.g., heroin, hydrocodone,

and oxycodone) who abruptly and completely discontinued opioids. The safety and efficacy of Lucemyra in the tapering context was not studied or proven, and thus the FDA expressly withheld the indication for that purpose. *Second,* the claim that Lucemyra is more effective or safer in treating withdrawal symptoms in any context is unsupported. *Third*, the statement that 192 pills are the ideal dose for patients is false. According to the Lucemyra label, the "usual" dose of Lucemyra should be no more than 96 pills, which is why USWM developed, and the FDA approved, the 96-pill bottle in the first place. *Fourth,* with respect to writing refills, there is no scenario where a patient who is abruptly discontinuing opioids needs or should be prescribed 192 pills plus a refill.

31. One particular off-label use that USWM sales representatives have been encouraged to sell to doctors is a use in connection with a drug called Sublocade. Sublocade, a brand drug, is an extended release form of buprenorphine, a partial opioid agonist that is used to replace short-acting opioids (e.g., heroin, hydrocodone, and oxycodone) in a tapering treatment regimen. Sublocade is administered once monthly through abdominal subcutaneous injection, and is gradually released into the body over that one-month period. Sublocade is, by its indication, to be administered to patients for multiple months as part of a long-term opioid discontinuation treatment plan.

32. As more and more doctors are switching patients from the shorter-acting dosage forms of buprenorphine to longer-acting Sublocade injections, USWM management has encouraged its sales representatives to prescribe Lucemyra to manage withdrawal symptoms that patients could experience as they adjust to the change in the dosage from buprenorphine pills to the extended release mechanism in Sublocade. Indeed, as will be described in Section IV(C) below, some USWM have teamed up with Sublocade sales representatives to co-promote Sublocade and Lucemyra as drugs that should be prescribed together, and have hired specific doctors to help them do so. Promoting Lucemyra to be used with Sublocade is a non-indicated, off-label use.

33. Plaintiff has obtained evidence of statements of USWM's management instructing him to sell the drug off label. For example, in a recorded conversation with Brown, Brown

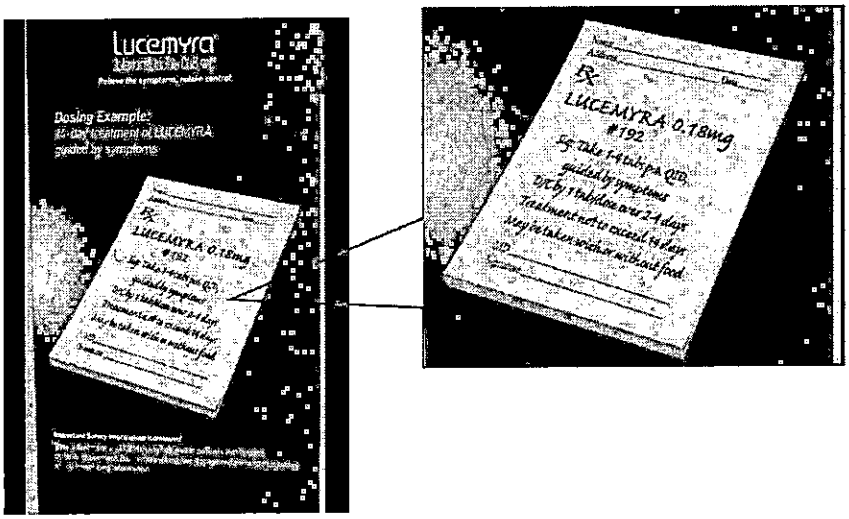
instructed Plaintiff how to effectively sell the drug for off-label uses by telling doctors they should:

> start low and go slow and test it.... [B]etter to have [Lucemyra] and not need it. Some of the patients... you are going to bring them down slowly [i.e., taper].... So you are going to need several phases. So better to have it, right? So give them 192 [pills]. It's not going to hurt them. It's not a narcotic. There's nothing wrong with it being around. And then also in the future if they do relapse you don't have to have some emergency supply for them.

USWM Further Promotes Off-Label Use Through Unapproved and Misleading Marketing Material.

34. To help persuade doctors to write for off-label and medically unnecessary uses, USWM developed false and misleading advertising directing doctors to write scripts for 192 pills or for extended periods of time. One example is in the form of a drawing of an exemplar script pad written for 192 Lucemyra pills that appears in a doctor brochure. USWM developed this advertising piece to create the false impression that a usual and acceptable prescription for Lucemyra is two bottles and instructed salespeople to tell doctors to write scripts based on the language of the exemplar script pad. USWM developed and disseminated this marketing material without seeking or receiving approval from the FDA.

35. The following is a copy of the unapproved, misleading dosing guide that USWM instructs its salespeople to show to doctors in support of getting doctors to write scripts for 192 pills (two bottles):



36. This marketing material is incompatible with the on-label dosage regimen for Lucemyra. As described above, clinical studies show that the withdrawal symptoms associated with abrupt discontinuation typically peak on day two and subside by days five through seven. USWM's representation that a typical patient may need 192 pills over a 14-day period is an outright falsehood—one that not only encourages wasteful prescribing, but, given the dangerous side effects associated with the drug, unnecessarily jeopardizes the health and safety of patients who are already vulnerable.

37. Notably, while USWM directs its salespeople to present doctors with this misleading script pad exemplar in the privacy of the doctors' offices, it does not display or disseminate this marketing materials in public forums. For example, on USWM's Lucemyra website there is a page dedicated to "dosing." That page shows the example of "3 tablets 4 times 7 days," consistent with the standard 96-pill bottle (when factoring in the additional two days of tapering off of Lucemyra). Thus, in public settings where USWM's advertising is likely to be noticed by the FDA, it advertises consistent with the indicated "usual" dose of Lucemyra, but when alone with prescribers away from the scrutiny of regulators, it pushes the non-indicated 192 pill dosing regimen.

38. This misleading marketing material forces the representatives to market off-label.

As one sales representative said to Plaintiff: "[W]hen the company is directing you to really [go off label] and now has marketing material to actually support it, it's almost impossible not to go [off label]."

39. In addition to the misleading script pad, USWM management directs its salespeople to present doctors with a non-approved study written by, among others, USWM's Chief Medical Officer to promote Lucemyra over clonidine. The article, entitled "*Differences in the Receptor Binding Profile of Lofexidine [Lucemyra] Compared to Clonidine,*" is a comparison of receptor binding affinity of Lucemyra and clonidine based on observations in various *in vitro* studies. The study concludes that while both drugs bind to certain alpha-adrenoceptors, Lucemyra also binds to dopamine and serotonin receptors, which is similar to the mechanism of anti-psychotic medications. The article also suggests that Lucemyra is safer because it bears less of a risk of hypotension than clonidine, even though Lucemyra itself also has a significant risk of hypotension and other side effects, including QT prolongation.

40. The article has not been approved by the FDA for dissemination to doctors, nor does USWM intend on seeking approval to market this article. This is because, by the express admission of USWM's Dr. Mark Pirner and regional sales director Brown, this article is "promotional" and lacks the scientific rigor needed to get FDA approval.

41. Despite lacking scientific rigor and FDA approval, USWM nevertheless encourages its salesforce to use this article as a selling point. To this end, while on sales calls, Plaintiff Aland has witnessed his manager, Brown, present this article to multiple doctors and say that it not only establishes that Lucemyra is safer than clonidine, it also establishes that Lucemyra has additional sedative, anti-anxiety, and anti-psychotic attributes similar to anti-psychotic medications. Brown did and does so despite knowing that it is inappropriate to market this unapproved study to doctors. Indeed, on the occasions that Brown has shared this article, he has told doctors he cannot leave it with them, but has encouraged them to take a picture of it with their phone so that they can access it at their leisure, which several doctors have done. Several other USWM employees have corroborated this practice by Brown in recorded conversations with Plaintiff.

USWM Pays Bribes to Doctors, Pharmacists, and Others to Induce and Facilitate Lucemyra Scripts.

42. Despite the illegal marketing efforts, given the insurance coverage obstacles described above, persuading doctors to prescribe Lucemyra is a tough sale at any dose, much less for twice the usual dosage. Therefore, USWM has resorted to bribery to get doctors to prescribe Lucemyra and to get their staff and others to obtain the necessary prior authorizations to get the drug covered by insurance, including Government healthcare plans.

43. One primary way in which Lucemyra bribes doctors is through "speaker programs," in which it pays doctors to promote Lucemyra to the medical community. Speaker programs by law, and by USWM's internal policies, may not be used to attempt to persuade doctors to write Lucemyra scripts. USWM's internal policies require, among other things, that (1) speakers have appropriate expertise, credentials, and ability to communicate to the targeted audience, (2) speakers not be engaged to establish a relationship, gain or improve access to the speaker, reward past prescribing, or induce future prescribing, (3) programs not be conducted for the benefit of the speaker, and that out-of-town speakers may only be used when there is a legitimate business reason to do so, (4) speakers present the approved slide deck, without any unapproved materials or modifications, and (5) speakers never proactively provide off-label information.

44. The speaker program, however, is a sham. USWM management and sales representatives routinely disregard all of the above policies, using the speaker programs as a way to induce and reward future and past prescribing and to spread off-label promotional messages about the drug.

45. USWM has engaged dozens of doctors to serve as promotional speakers. In 2019 alone, several of these doctors have had over 40 speaking engagements, some being paid $75,000 or more. The purpose of these payments is to induce the doctors to prescribe Lucemyra. During multiple calls, including weekly sales calls, USWM sales directors, including regional director Brown, have compared USWM's investment in a particular doctor's speaking engagements to the number of Lucemyra scripts that the doctor has written. When the doctors

do not write a sufficient amount of scripts compared to their speaking engagement fees, Brown has repeatedly stated that the "return on investment" or "ROI" does not justify any more speaking engagements with that particular doctor. When, however, a doctor has written a sufficient number of prescriptions compared to their speaking engagement fees, Brown comments positively on the doctor and assists the particular sales representative in securing more engagements for the doctor.

46. Importantly, USWM closely tracks the prescribing habits of all of its speakers. It collects, analyzes, and distributes weekly attainment data that shows the number of scripts written, the doctors writing the scripts, the number of pills each doctor prescribed, and what healthcare plan paid for each script. USWM sales managers use this information to assess whether a doctor is writing sufficient scripts to justify continued speaking engagement fees.

47. Particular examples of doctors being paid improper speaking fees will be described in Section IV(C) below. But the true motives behind USWM's speaker program are acutely demonstrated by one particular example involving Plaintiff. In November 2019, Plaintiff was approached by one of the doctors that he called on—Muhammad Arif, MD, a specialist in pain medicine for the University of Pittsburgh Medical Center. Dr. Arif told Plaintiff that he wanted USWM to pay for a holiday party for him and his staff (consisting of about 15 people) at a high-end seafood restaurant in Warrendale, Pennsylvania. Plaintiff went to his manager, Brown, and told him about the request. Brown immediately said that they would set up a speaker program where Dr. Arif and his staff would attend as the "audience." The speaker they selected was Anace Said, M.D.—a primary care physician from Wellington, Connecticut, who is one of Lucemyra's heaviest prescribers, and had already been compensated for over 40 speaker programs. (Dr. Said will be discussed in more detail in Section IV(C) below). To make the trip "worth his while," Brown said he would set up two speaking engagements that day, both a lunch and then the dinner at the seafood restaurant.

48. Brown immediately began making arrangements for the "speaking engagement." Plaintiff, however, purposefully avoided confirming the arrangements, as he knew that the speaking engagement was a ruse to finance Dr. Arif's office Christmas party. While Plaintiff

ensured that the Christmas party did not happen, this example demonstrates that USWM's speaker program is a sham.

49. In addition to bribing doctors, as will be discussed in more detail below, Lucemyra has paid under-the-table cash bribes to pharmacists in return for completing prior authorizations, as well as representatives from other drug companies to promote and sell Lucemyra.

USWM Salespeople Collude with Doctors and Pharmacists to Make False Representations to Get Prescriptions Covered.

50. In addition to the conduct described above, USWM staff has encouraged and helped prescribers, their staff, and pharmacists to make false representations to get Lucemyra scripts approved for payment.

51. USWM salespeople have, for example, provided multiple prescribers with canned letters of medical necessity containing language that USWM knows, from experience, will get the prescriptions covered. These letters include false and unproven statements about Lucemyra's superior efficacy and safety profile compared to clonidine, and that the patient in question either cannot tolerate clonidine or has failed it in the past. USWM has told doctors to just submit these letters, even when the doctors have not verified whether the patient is in fact intolerant to or has failed clonidine. Some specific examples will be discussed in section IV(C) below.

52. Additionally, USWM salespeople have encouraged prescribers to check boxes indicating prior clonidine failure even when the prescribers and their staff do not know and cannot get this information. This is because commonly patients do not know whether they have ever taken clonidine, and there are often no medical records supporting prior clonidine use. But USWM salespeople have been instructed by managers to tell prescribers and their staff that they can assume that these patients have tried clonidine before, reasoning that because the patients have been on so many drugs in their past, it is likely that they have been prescribed clonidine at some point. Plaintiff has witnessed his manager, Brown, state this to prescribers and their staff on many occasions. Other specific examples of this misconduct will be described in section IV(C) below.

53. Additionally, as described in section IV(C) below, USWM salespeople have also recruited pharmacists to pose as prescribers and fabricate patients' medical history to get Lucemyra approval.

USWM's Unlawful Conduct Has Resulted in a Significant Spike in Double Scripts

54. The conduct described above has served its intended purpose—doctors are writing more Lucemyra scripts, and, significantly, they are writing more scripts for two or more 96-pill bottles.

55. This evidence is demonstrated by USWM's quarterly attainment data. According to this data, in quarter one of 2019, approximately 3.1 percent of the total number Lucemyra scripts written were double scripts for 192 pills. In the second quarter of 2019, the number of double scripts increased slightly to approximately 3.5 percent. Then, in the third quarter of 2019, the percentage of double scripts nearly tripled to 9.2 percent. And so far in quarter four for 2019, with approximately 88 percent of the days booked, the percentage of double scripts has increased to approximately 12.9 percent, which is more than a four-fold increase from the statistics in quarter one.

C. Specific Examples of Improper Marketing, Bribery, and Material Misrepresentations.

56. Plaintiff has gathered evidence of multiple USWM employees engaged in the illegal conduct described above. The following are some examples of specific representatives who have engaged in illicit conduct.

USWM Salesperson Liz Farrell

57. Liz Farrell is a sales representative based in New York City, New York. Farrell has engaged in several illegal practices. One of the illegal practices is a scheme whereby she bribes a pharmacy technician to fabricate information necessary to get Lucemyra scripts approved for coverage by healthcare plans, including Government healthcare plans.

58. The scheme works as follows. Farrell has developed a relationship with a pharmacy technician at a pharmacy located in New York City, called Ahma Rx. The pharmacy technician provides Farrell with business cards and customized script pads for Ahma Rx, which

Farrell then provides to prescribers, informing the doctors where to send the script and the patients how to call the pharmacy and arrange for free delivery of the drug.

59. When the doctors send the script to Ahma Rx, the pharmacy technician handles the prior authorization with the help and assistance of Farrell. In so doing, the pharmacy technician shares with Farrell private patient information, including the patient's name and date of birth, the disclosure of which is forbidden by the Health Insurance Portability and Accountability Act ("HIPPA").

60. To get the prior authorization, the pharmacy technician fills out documents in the prescriber's name, and fabricates information concerning the patient's medical history. The fabricated information includes a misrepresentation that the patient has failed or is intolerant to clonidine.

61. Additionally, when required, the pharmacy technician provides to the insurer a canned letter of medical necessity that Farrell developed for the pharmacy technician. This canned letter of medical necessity is forged in the prescriber's name, and includes misrepresentations that (1) the patient will be undergoing abrupt discontinuation of opioids, when in fact that patient is tapering, (2) that the patient cannot be on clonidine due to adverse effects of hypotension associated with clonidine (despite the fact that Lucemyra has the same side effect); and (3) that the patient has tried clonidine before and that it has been either ineffective or caused side effects which resulted in the discontinuation of therapy. The pharmacy technician submits this information without the approval of the doctor, and without verifying with the doctor whether the information contained in the letter is true.

62. In exchange for the pharmacy technician's services, Farrell pays her a per-script fee of $15.00. She transfers the cash to the technician via a Venmo account.

63. Farrell disclosed this information to Plaintiff in a series of recorded phone conversations and text messages in which she attempted to recruit Plaintiff to set up a similar arrangement with the pharmacy technician. Farrell admitted all of the above, including that the pharmacy technician fabricates the patients' medical history to get approval:

Plaintiff: And then obviously New York is the same as Pennsylvania where [you need] a clonidine failure in most cases. And she does that?

Farrell: Right, yeah, yeah.

Plaintiff: And she pushes that letter?

Farrell: That's what that letter says, mhmm.

Plaintiff: And she wouldn't need the doctor for that, she just does it?

Farrell: Yep. Now I didn't say that out loud, but… [laughter].

64. In addition to her scheme with Ahma Rx, Farrell pays bribes to sales representatives from other drug companies to promote Lucemyra with the doctors within their network. One such person is a sales representative from Salix Pharmaceuticals who sells Relistor, a drug indicated to treat opioid-induced constipation. In exchange, Farrell pays the Salix representative a percentage of the commission that she earns on any Lucemyra script prescribed by one of the Salix representative's doctors. Farrell admitted to this arrangement in a recorded conversation with Plaintiff.

65. Additionally, Farrell engages in illegal marketing with the doctors upon which she calls. In addition to the off-label marketing practices described above, Farrell shows some doctors internal USWM data showing the sales statistics of USWM salespeople, including the number of scripts that have been credited to each representative, and the amount of pills each doctor is prescribing per script. She shows this data to her doctors and asks them to write more scripts for 192 or more tablets to help her get her numbers up.

66. For example, in a recorded conversation where Farrell recounted one of these conversations with Joseph Casarona, M.D.—a neurologist in New York City—she told Plaintiff:

I'm like look at this guy in Atlanta [USWM salesperson Keith Cates]. And he's like, 'what the hell is he doing?' And I'm like it's basically one doctor but he's writing four hundred something pills at a pop. And he goes 'well how the hell is that right?' And I'm like it's not. [Laughter]. But the rep don't f**ng care. [Laughter].

***

I showed him the data and I just said… I need a boost here…. And I'm like I'm third from the bottom and … it's the end of the year and companies like pharmaceuticals they do cuts and I can't afford to be without a job. And so he's like I'm going to help you.

***

So he sends in three to [the Ahma Rx pharmacy technician] and both doubles—192. One got straight [through] without denying. One so far is approved and she's working on the other. So see the sob stories work [laughter].

67. According to company data, Farrel's illegal conduct has caused over 100 scripts to be reimbursed by Government programs, including Medicare and Medicaid.

USWM Salesperson Jennifer Oehler

68. Jennifer Oehler is a salesperson based in Hartford, Connecticut. She too engages in several illegal practices in connection with the sale of Lucemyra. Despite having no prior experience in the opioid, pain medicine, or addiction space, Oehler is one of USWM's top salespeople. She has received that status due primarily to one doctor—Anace Said, M.D., a primary care physician based in Wellington, Connecticut. Dr. Said routinely prescribes Lucemyra at 192 pills, plus refills, for off-label, medically unnecessary reasons. He does so because of lucrative "speaking programs" that USWM routinely pays him to perform.

69. Oehler was referred to Dr. Said through a sales representative from Indivior PLC that sells Sublocade. She was informed by the sales representative that Dr. Said will write scripts in return for getting speaking engagements. Therefore, Oehler and the Indivior sales representative agreed to collaborate and set up speaking engagements for Said where he would co-promote Sublocade and Lucemyra in the same speaking engagement. Dr. Said is often paid by *both* the USWM and Indivior for the *same* speaking engagement where he promotes both drugs.

70. Notably, Dr. Said lacks important qualifications to serve as a speaker for Lucemyra. According to USWM's policies a speaker must have appropriate expertise,

credentials, and ability to communicate to the targeted audience. Dr. Said is a general practitioner with no specialization in addiction or pain management. He is also unfamiliar with and unable to communicate the scientific aspects of the drug. He also is a poor communicator in group settings. For these reasons, several employees at USWM objected to approving him as an authorized speaker. Despite these objections, however, Dr. Said was approved as a speaker to reward him for writing past scripts and to induce him to write more.

71. In 2019 to date, Dr. Said had 40 or more speaking engagements promoting Lucemyra where he receives $1,500 to $2,000 per engagement. Upon information and belief, Dr. Said has been paid near or more than a total of $75,000 in 2019 by USWM for these engagements. Upon information and belief, he has had the same amount of engagements for promoting Sublocade and has received a similar amount from Indivior, often for the same speaking engagement where he was paid by USWM for promoting Lucemyra.

72. Dr. Said's speaking engagements usually occur in small office settings with only two or three audience members. Per USWM's policy, when speaking at these events Dr. Said is supposed to present a company-approved slide deck, not materially veer from the approved materials during the presentation, and never proactively discuss off-label uses of the product. The approved slide deck consists of over 40 slides, with discussions of, among other things, Lucemyra's indication, supporting science and neurobiology, and appropriate dosing—i.e., one bottle of 96 pills taken over 9 days.

73. Dr. Said, however, does not present the slide deck. Indeed, in a recorded conversation with Plaintiff, Oehler admitted that Dr. Said does not know and cannot articulate the science underlying Lucemyra. Instead, Dr. Said, with the guidance of Oehler and her manager, Brown, has cherry picked one or two slides from the presentation, and he spends the time discussing how, among other things, he uses the medication with his patients as part of a tapering treatment plan, which, of course, is off label. Oehler admitted that she knew she should not be discussing using Lucemyra in a tapering context, but that Dr. Said does so anyway. In discussing Dr. Said's presentation, she said: "And so [Dr. Said] did like a taper.... I don't say this, but [Dr. Said] can. He's like he tapered [his patient] but helped him in that process with

Lucemyra.... [A]nd Dr. Said followed up with him the next day. And [the patient] had said to Dr. Said that that was the first time in a long time that he got six hours of sleep."

74. These lucrative speaking engagements have caused Dr. Said to prescribe hundreds of bottles of Lucemyra for off label and medically unnecessary uses, which have been paid by Government healthcare plans. Indeed, according to Oehler, Dr. Said writes Lucemyra scripts automatically every time he prescribes buprenorphine medications (like Suboxone) or administers buprenorphine injections (Sublocade). He does so, according to Oehler, "just in case" the patient at some point in the future misses their appointment and he is unable to prescribe or administer buprenorphine, and the patient goes through withdrawals. He even prescribes it, according to Oehler, during buprenorphine inductions, even when patients represent that they are not currently on opioids, and even when he has no evidence that the patient is lying (he does not conduct rapid drug screens), just in case the patient is not telling the truth and might go through withdrawals.

75. Dr. Said also, as a matter of practice, writes for two bottles of Lucemyra and one refill. Again, he does so despite the fact that patients are already on a maintenance opioid regimen, just in case a patient may suffer withdrawals sometime in the future.

76. In addition to writing unnecessary prescriptions, Dr. Said, at the direction of Oehler, affirmatively misrepresents to insurers, including Government health plans, that, among other things, the patients for whom he prescribes Lucemyra have tried and failed or are intolerant to clonidine. Oehler admitted to this in a recorded conversation with Plaintiff:

Plaintiff: So have you... had to just like have somebody just say—I don't even know how to say it without making it sound bad—they just assume that the patient had failed clonidine in the past but don't really know?

Oehler: Yeah, [Dr.] Said does it all the time.

77. According to company data, Oehler's illegal conduct has caused over 120 scripts to be reimbursed by Government programs, including Medicare and Medicaid.

USWM Salesperson Jackie Guagenti

78. Jackie Guagenti is a USWM salesperson based in Columbus, Ohio. She too engages in illegal marketing practices, and counsels doctors and their staff how to make misrepresentations to get Lucemyra scripts filled.

79. In a recorded conversation with Plaintiff, Guagenti admitted that she markets Lucemyra off-label to get doctors to write higher pill counts to meet her company-mandated sales quotas. She tells doctors that "historically [patients] are doing better with a longer [Lucemyra] regimen" and that they should write for two or more bottles, prescribing low doses over an extended period of time beyond the 14-day maximum in the label.

80. In a recorded conversation, she further described her off-label marketing tactics as follows:

> I have addiction guys in my pocket already because I have been doing addiction for nine years.... [L]ike that is where it is a goldmine, because in addiction... we talk about buprenorphine, when its coming off the receptor it doesn't seem to be as bad as on day one through five, but the duration of it is long, it's still lingering around for a few weeks or so. They buy right into that.

81. These marketing tactics, according to Guagenti have succeeded in getting doctors to write prescriptions for two, and, in some cases, over three bottles of Lucemyra in a single script: "And [the doctors] they're like... I agree with that. And then all of a sudden I had 13 people and I'm like holy sh*t. The last couple of weeks I have had people in the 200[s], and today I had one come through for 300 and some tablets."

82. To facilitate scripts, in particular prescriptions covered by Medicaid, Guagenti has made an arrangement with a pharmacy in Ohio, called Buckeye Pharmacy. The pharmacy handles all of the prior authorization work. To facilitate this, Guagenti has obtained from her prescribers a canned letter of medical necessity that the pharmacy uses in every case to support the use of Lucemyra. The canned letter of medical necessity states, among other things, that the patient has tried and failed or not tolerated clonidine in the past.

83. Although the canned letter of medical necessity states that the patient tried and

failed clonidine, in reality many patients do not know whether they have taken clonidine, and have no medical history supporting prior clonidine use. So, Guagenti instructs her prescribers and their staff to falsely chart in every case that the patient has tried and failed clonidine, telling them that they can just assume so.

84. She has gone so far as to instruct and encourage her prescribers and staff to manipulate patients to get them to say they have tried and failed clonidine even when the patients do not know. For example, in a recorded interview with Plaintiff, Guagenti stated:

> [T]he nurse or the [physician assistant] and one of the… office staff they kind of nod their head [to the patients]—have you taken clonidine before? And [the patients] are like yes. Did it work? And [the staff] are shaking their heads no. And [the patients] are like no. And [the staff] are like okay. So they chart the notes.

85. According to company data, Guagenti's illegal conduct has caused over 60 scripts to be reimbursed by Government programs, including Medicare and Medicaid.

USWM Salesperson Nathan Deck

86. Nathan Deck is a USWM salesperson based in Philadelphia, Pennsylvania. He too has engaged in illegal marketing practices, including arranging speaking engagements for doctors to induce the doctors to write Lucemyra prescriptions.

87. One such illegal arrangement is with David Lichten, M.D., who specializes in, among other things, pain medicine. In 2019, Deck has scheduled over 40 speaking engagements for Dr. Lichten, for which Dr. Lichten has been paid at least $75,000 by USWM.

88. USWM has tracked the amount of scripts attributed to Dr. Lichten, and has been unhappy with the amount of Lucemyra prescriptions Dr. Lichten has written. The company has refused to grant more speaking engagements to Dr. Licthen despite his pleas to get more. One of reasons USWM has elected not to grant Dr. Lichten more speaking engagements is because of his low Lucemyra script count. Plaintiff has heard his managers on multiple occasions say that Dr. Lichten was not worth the speaker program investment because of the lack of scripts he wrote. For example, in a recorded conversation, Plaintiff's manager, Brown, stated: "And so I

talked to Nate [Deck] about [getting Lichten more programs]. You have literally done the most programs. And the other part is if the numbers don't react, we can't do that many again."

89. Despite the fact that USWM has elected not to extend any more speaker programs to Dr. Lichten, Deck continues to entice Dr. Licthen with the promise of more speaker engagements in 2020 to get him to write more scripts. For example, in a recorded conversation with Plaintiff, Deck stated:

> I mean I tried incentivizing Lichten and look at that. I mean I think he is a decent guy and at times he has merit, but I barely got two [scripts] out of him, and he just sent me a text this morning and he was asking [for more speaker engagements in 2020 and] to get January off to a fast start. And I'm like hey man, I'm all about it. I want to hit the ground running—keep this doggy moving. And I obviously know we are not going to be doing it.... But, yeah, that gravy train is over for him.

Other USWM Salespeople

90. The conduct described herein is not isolated to the individuals described above. There are many in USWM's salesforce whose doctors are writing an excessive amount of prescriptions for two or more bottles, which is the result of the unlawful practices described above.

91. For example, USWM salesperson, Keith Cates, based in Atlanta, Georgia, has consistently led the country in doctors who write for 192 pills or greater. For example, in the third quarter of 2019, Cates received credit for 369 Lucemyra scripts, even though his doctors only wrote 256 prescriptions, meaning that approximately 44 percent of his total actual scripts were for more than one 96-pill bottle of Lucemyra. Similarly, to date in the fourth quarter of 2019, with 88 percent of the days booked, Cates has received credit for 293 prescriptions based on only 194 actual scripts, meaning that approximately 51 percent of his total actual scripts were for more than one 96-pill bottle.

92. Similar trends exist for USWM Salespeople Shannon Sanders, based in Detroit, Michigan; Curtis Goodman, based in Chicago, Illinois; as well as Oehler, Guagenti, and Farrell

as described above.

93. According to USWM attainment data, a significant portion of these double prescriptions were reimbursed by Medicare, Medicaid, and other Government health plans.

D. USWM Violated Laws and Regulations Forbidding Off-Label Marketing and Kickbacks.

USWM Violated Laws and Regulations Forbidding Off-Label Marketing.

94. The FDA regulates drugs based on "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a).

95. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drugs' intended uses are safe and effective. *See* U.S.C. § 355. With very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, i.e., "indications," not approved by the FDA. "Off-label" refers to the marketing of an FDA-approved drugs for uses that have not undergone FDA review and approval, i.e., for purposes not approved by the FDA.

96. With the exception of purely scientific medical information provided by qualified medical professionals, sales and marketing presentations, promotions or marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the FDA. *See* 21 U.S.C. §§ 331(a)-(b), 352(a), (f). Additional proscribed marketing activity includes any attempts by pharmaceutical salespeople to solicit discussion with physicians concerning off-label use.

97. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process and removes the incentives to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity of its use.

98. Pursuant to the Food, Drug and Cosmetics Act ("FDCA") 21 U.S.C. §§ 301, *et seq.*, the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved

prescription drugs.

99. The FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product as "misbranding." 21 U.S.C. § 321(n). Labelling includes, among other things, brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio-visual material. 21 C.F.R. § 202.1(l)(2).

100. The FDA regulations deem "advertising" to include media-based activities that appear in magazines, newspapers, professional journals and on television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(l)(1). Courts have consistently held that oral statements made by a company's salesperson relating to a pharmaceutical product constitute commercial advertising and promotion.

101. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the FDCA, 21 U.S.C. §§ 301, 321, 331, 352, 360b, 371; 21 C.F.R. § 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

102. Prescriptions for off-label uses are generally not eligible for reimbursement under Government health care programs, including Medicare and Medicaid programs.

103. USWM's off-label marketing practices described above, including its promotion of two or more Lucemyra 96-bottles for tapering and medically unnecessary reasons, such as prophylactically "just in case" a patient in the future suffers some withdrawal symptoms, violated the above-described laws and regulations, which in turn violated the FCA. USWM's unlawful activity induced physicians to prescribe Lucemyra for prescriptions paid by Government healthcare plans, when physicians otherwise would not have done so. Had the Government known about the off-label uses for which Lucemyra was prescribed, it would not have paid for the prescriptions.

USWM Violated Laws and Regulations Forbidding Payment of Kickbacks.

104. The Anti-Kickback Statute ("AKS") forbids anyone from knowingly and willfully paying or offering to pay any renumeration, including kickbacks, bribes, or rebates, directly or indirectly, overtly or covertly, in cash or kind to any person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment be made in whole or in part under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(B). A claim that results from a violation of the AKS constitutes a false or fraudulent claim under the FCA. 42 U.S.C. § 1320a-7b(h).

105. USWM paid and offered to pay renumeration to purchase and order, and arrange or recommend ordering and purchasing Lucemyra scripts paid by Government healthcare plans, including Medicare and Medicaid. The illegal renumeration included:

- Lucrative payments to doctors disguised as payments for "speaking programs" designed to induce doctors to write Lucemyra scripts;
- Cash payments to pharmacy employees to induce them to help arrange for the purchase of Lucemyra by managing the prior authorization process;
- Cash payments to non-USWM pharmaceutical representatives in exchange for their promoting Lucemyra to doctors;
- Co-promotional services to other pharmaceutical companies, whereby USWM salespeople would promote the drugs of other pharmaceutical companies (e.g. Sublocade) in exchange for those representatives promoting Lucemyra; and
- Free services to prescribers of Lucemyra in the form of providing and arranging for the provision of time-consuming prior authorization services to facilitate the approval of Lucemyra scripts.

106. While there are certain safe harbor provisions in the AKS, none apply here. Importantly, the purpose of all of the above remunerations was to induce the recipient of the remuneration to promote or prescribe Lucemyra, or to arrange for the reimbursement of Lucemyra by Government healthcare programs, including Medicare and Medicaid.

107. The illegal kickbacks described above caused Lucemyra to be submitted to and

paid by Government healthcare programs in violation of the FCA.

E. USWM Caused Thousands of False Claims to Be Submitted Against the Government.

108. A substantial percentage of Lucemyra scripts dispensed to date—nearly half—have been reimbursed by Government healthcare programs. This has amounted to thousands of scripts.

109. Prior to reimbursement of these scripts, physicians, pharmacies, pharmacy benefit managers, and Medicare and Medicaid plan sponsors all certified that the information submitted, including the prior authorization information, was truthful and accurate; that the prescriptions were medically reasonable and necessary; and that they had complied with all applicable Medicare and Medicaid laws and regulations, which includes AKS laws and laws forbidding off-label marketing.

110. As described in more detail above, these representations were false. USWM caused the physicians, pharmacies, pharmacy benefit managers, and Government plan sponsors to make these false representations. USWM knew that it was doing so, as it closely tracked the number of scripts reimbursed by Government plans, and the amount of money it received from the Government for Lucemyra.

111. These false representations were material to the Government's decision to cover the Lucemyra scripts. Had the Government known of these false representations, it would not have paid.

V. CLAIMS FOR RELIEF

Count 1—Against All Defendants for Violations of the False Claims Act; Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

112. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

113. Relator seeks relief against USWM under Section 3729(a)(1)(A) of the FCA. 31 U.S.C. § 3729(a)(1)(A).

114. As a result of USWMs' illegal substitution policies, USWM has caused false and

fraudulent claims for payment to be presented to federal health care programs.

115. Accordingly, USWM knowingly caused false or fraudulent claims to be presented for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

116. The false and fraudulent statements and omissions that USWM made in connection with these false and fraudulent claims were material, as they had a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. Indeed, had the federal healthcare programs been aware of the false and fraudulent nature of the claims, statements, and omissions, the claims would not have been paid.

117. By reason of the false or fraudulent claims that USWM knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages, plus a civil monetary penalty for each false claim.

Count 2—Against All Defendants for Violation of the False Claims Act; Use of False Statements (31 U.S.C. § 3729(a)(1)(B)

118. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

119. As a result of USWM's illegal substitution policies, USWM knowingly made and/or caused others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

120. More specifically, USWM made or caused others to make false certifications and representations that the reimbursements it sought for illegally substituted drugs were in full compliance with applicable federal and state laws prohibiting illegal substitutions, were not the product of fraudulent practices, and were for reasonable and medically necessary reasons. Those false certifications, statements, and representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

121. By reason of the false or fraudulent claims that USWM knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial

amount to be determined at trial, and is entitled to recover treble damages, plus a civil monetary penalty for each false claim.

Count 3—Against All Defendants for Violation of the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 20-77-911

122. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

123. USWM violated the Arkansas Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Arkansas as described herein.

124. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Arkansas.

125. The State of Arkansas, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Arkansas would not otherwise have paid.

126. By reason of these payments, the State of Arkansas has been damaged, and continues to be damaged, in a substantial amount.

Count 4—Against All Defendants for Violation of the California False Claims Act, Cal. Gov't Code §§ 12650-12656

127. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

128. USWM violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

129. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

130. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of California would not otherwise have paid.

131. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

Count 5—Against All Defendants for Violation of the Colorado Medicaid False Claims Act, Col. Rev. Stat. Ann. §§ 25.5-4-303.5 – 25.5-4-310

132. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

133. USWM violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado as described herein.

134. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

135. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Colorado would not otherwise have paid.

136. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

Count 6—Against All Defendants for Violation of the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-272 – 4-289

137. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

138. USWM violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut as described herein.

139. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

140. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Connecticut would not otherwise have paid.

141. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

Count 7—Against All Defendants for Violation of the Delaware False Claims and Reporting Act, Del. C. Ann. Tit. 6 §§ 1201-1211

142. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

143. USWM violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware as described herein.

144. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

145. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Delaware would not otherwise have paid.

146. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

Count 8—Against All Defendants for Violation of the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2.381.10

147. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

148. USWM violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia as described herein.

149. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

150. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims, which the District of Columbia would not otherwise have paid.

151. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

Count 9—Against All Defendants for Violation of the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092

152. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

153. USWM violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

154. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

155. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Florida would not otherwise have paid.

156. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

Count 10—Against All Defendants for Violation of the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6

157. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

158. USWM violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia as described herein.

159. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

160. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Georgia would not otherwise have paid.

161. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

Count 11—Against All Defendants for Violation of the Hawaii False Claims to the State Act, Hawaii Rev. Stat. §§ 661-21 – 661-31

162. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

163. USWM violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii as described herein.

164. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

165. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Hawaii would not otherwise have paid.

166. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

Count 12—Against All Defendants for Violation of the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1-175/8

167. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

168. USWM violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois as described herein.

169. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

170. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Illinois would not otherwise have paid.

171. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

Count 13—Against All Defendants for Violation of the Indiana False Claims Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11.5.5-18

172. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

173. USWM violated the Indiana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana as described herein.

174. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

175. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Indiana would not otherwise have paid.

176. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

Count 14—Against All Defendants for Violation of the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7

177. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

178. USWM violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa as described herein.

179. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

180. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Iowa would not otherwise have paid.

181. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

Count 15—Against All Defendants for Violation of the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16

182. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

183. USWM violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana as described herein.

184. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana

185. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Louisiana would not otherwise have paid.

186. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

Count 16—Against All Defendants for Violation of the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. §§ 8-801 – 8-811

187. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

188. USWM violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland as described herein.

189. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

190. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Maryland would not otherwise have paid.

191. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

Count 17—Against All Defendants for Violation of the Massachusetts False Claims Law, Mass. Gen. Laws Ann. Ch. 12, §§ 5A – 5O

192. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

193. USWM violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Massachusetts as described herein.

194. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Massachusetts.

195. The State of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Massachusetts would not otherwise have paid.

196. By reason of these payments, the State of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

Count 18—Against All Defendants for Violation of the Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615

197. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

198. USWM violated the Michigan Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan as described herein.

199. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

200. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Michigan would not otherwise have paid.

201. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

Count 19—Against All Defendants for Violation of the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16

202. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

203. USWM violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota as described herein.

204. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

205. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Minnesota would not otherwise have paid.

206. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

Count 20—Against All Defendants for Violation of the Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416

207. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

208. USWM violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana as described herein.

209. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

210. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Montana would not otherwise have paid.

211. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

Count 21—Against All Defendants for Violation of the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250

212. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

213. USWM violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada as described herein.

214. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

215. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Nevada would not otherwise have paid.

216. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

Count 22—Against All Defendants for Violation of the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61-B – 167:61-E

217. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

218. USWM violated the New Hampshire Medicaid Fraud and False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Hampshire as described herein.

219. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the New Hampshire.

220. The State of Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Hampshire would not otherwise have paid.

221. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

Count 23—Against All Defendants for Violations of the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18

222. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

223. USWM violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey as described herein.

224. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

225. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of New Jersey would not otherwise have paid.

226. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

Count 24—Against All Defendants for Violation of the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and New Mexico Medicaid False Claims Act, §§ 27-14-1 – 27-14-15

227. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

228. USWM violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico as described herein.

229. As a result of the misconduct alleged herein, USWM knowingly made, used, or

caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

230. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of New Mexico would not otherwise have paid.

231. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

Count 25—Against All Defendants for Violation of the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194

232. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

233. USWM violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York as described herein.

234. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

235. The State of New York , unaware of the false or fraudulent nature of these claims, paid such claims, which the State of New York would not otherwise have paid.

236. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

Count 26—Against All Defendants for Violation of the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618

237. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

238. USWM violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina as described herein.

239. As a result of the misconduct alleged herein, USWM knowingly made, used, or

caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

240. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of North Carolina would not otherwise have paid.

241. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

Count 27—Against All Defendants for Violation of the Oklahoma False Claims Act, Okl. Stat. Ann. Tit. 63, §§ 5053 – 5054

242. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

243. USWM violated the Oklahoma False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma as described herein.

244. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

245. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Oklahoma would not otherwise have paid.

246. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

Count 28—Against All Defendants for Violation of the Rhode Island False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9

247. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

248. USWM violated the Rhode Island False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island as described herein.

249. As a result of the misconduct alleged herein, USWM knowingly made, used, or

caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

250. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Rhode Island would not otherwise have paid.

251. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

Count 29—Violation of the Tennessee False Claims Act, Tenn. Code Ann. §§4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 75-5-181 – 75-5-185

252. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

253. USWM violated the Tennessee False Claims Act and Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee as described herein.

254. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

255. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Tennessee would not otherwise have paid.

256. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

Count 30—Against All Defendants for Violation of the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132

257. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

258. USWM violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas as described herein.

259. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

260. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Texas would not otherwise have paid.

261. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

Count 31—Against All Defendants of the Vermont False Claims Act, Vt. Stat. Ann. Tit. 32, §§ 630-642

262. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

263. USWM violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Vermont as described herein.

264. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

265. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Vermont would not otherwise have paid.

266. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

Count 32—Against All Defendants for Violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.1

267. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

268. USWM violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Virginia as described herein.

269. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Virginia.

270. The State of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Virginia would not otherwise have paid.

271. By reason of these payments, the State of Virginia has been damaged, and continues to be damaged, in a substantial amount.

Count 33—Against All Defendants for Violation of the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130

272. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

273. USWM violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington as described herein.

274. As a result of the misconduct alleged herein, USWM knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

275. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims, which the State of Washington would not otherwise have paid.

276. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Aland requests that judgment be entered against USWM as follows:

(1) Treble the Federal and Plaintiff State Government's damages in an amount to be determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statutes set forth above;

(2) Plaintiff Aland's reasonable attorneys' fees and costs;

(3) The maximum Relator award available under the FCA and equivalent false claims statutes of the Plaintiff States described above; and

(4) For any further relief the Court deems appropriate.

VII. DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial for all claims so triable.

Dated: December 27, 2019

Respectfully Submitted,

By: /s/ James D. Weakley
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